

**REMARKS**

Applicant has carefully reviewed the Office Action dated January 21, 2010 and has revised the claims according to the issues raised in that Action.

Claims 1-11, 20, 21, and 40-43 would remain in the case upon entry of this response, of which only claim 1, 11, 20, 21, and 40 are independent claims. The remaining previously pending claims have been canceled without disclaimer or prejudice to prosecuting their subject matter in other patent applications.

*A central issue underlying the Section 102 rejections is the importance of the terms “screener”, “screening”, and “screening test” used in this application and its claims. Screening tests are not diagnostic threshold tests. These terms are universally recognized as having specific meanings in the field of Audiology*

Screening tests are generally quick tests that are done to establish if an infant has normal or abnormal hearing. In the case of abnormal hearing, where the screening test “fails”, the patient is referred to an audiologist for diagnostic work-up which can include diagnostic threshold type tests that have been described in prior patent filings by the Applicant.

In the field of audiology, screening tests and diagnostic tests are two distinct categories. This is true across the clinical, industrial, scientific, and regulatory bodies involved in this field. Diagnostic tests such as ASSRs and other tests are used after initial hearing screening tests indicate the presence of hearing loss and abnormal hearing.

Guidelines for hearing testing show that the ASSR tests are done after infants are referred from a newborn hearing screening program. The thresholds evaluated during the diagnostic phase of the tests are different from the simple normal/abnormal results obtained during the early screening phase (e.g. “Guidelines for the early audiological assessment and management of babies referred from the newborn hearing screening program. Version 1.1 March 2007 NHSP Clinical Group.” (**NPL-REF A**)). As the title suggests, the purpose of this reference document is to define what to do when abnormal hearing is detected. In this case abnormal hearing is determined first and these babies are then referred from the newborn hearing screening program in order to have audiological assessment including various diagnostic/threshold tests.

The American Speech Language Hearing Association (ASHA) describes that hearing screening should be done first and then followed up by diagnostic hearing tests in the cases where abnormal hearing is found. Hearing screening quickly provides a pass or fail result which indicates normal or abnormal hearing. Although threshold tests can also have pass/fail results for different ASSRs this will simply tell you that an infant can not hear at a particular level and that this level may be considered the patient's threshold level (although this may be elevated in the case of hearing loss). Diagnostic testing is part of this second group of tests and is distinct from screening. (**NPL-REF B**)).

A recent article entitled, Objective assessment of frequency-specific hearing thresholds in babies (*International Journal of Pediatric Otorhinolaryngology*, Volume 68, Issue 7, Pages 915-926 H.Luts, C.Desloovere, A.Kumar, E.Vandermeersch, J.Wouters) states that "After a failed hearing screening and referral to more specialized medical services an extensive audiological evaluation has to ascertain the hearing status of the referred infant. It is important to obtain a quantitative measure of the hearing thresholds in order to start appropriate multidisciplinary intervention." (**NPL-REF C**)).

Accordingly, applicant believes that "screening" is recognized by persons skilled in the art in the field of Audiology as a pass/fail test different from diagnostic tests done on some patients after the pass/fail test.

### ***Claim Objections***

In claim 20, "lest" has been changed to "least" to overcome the objection.

### ***Double Patenting***

Claims 1-4, 7-9, 21, and 40-41 were rejected for "same invention" double patenting. In light of the amendments made hereby, it is submitted that the "same invention" double patenting rejection does not apply to the claims that would remain pending after entry of this response.

***Claim Rejections - 35 USC § 101***

Claims 1-11, 20, and 40-43 were rejected as directed to non-statutory subject matter. Each of independent claims 1, 11, 20, 21 and 40 in this group of claims has been amended to ensure that it is directed to statutory subject matter. As evident from Figs. 1a and 1b and the original specification, the analysis of the acquired results are performed by computer-implemented means as these calculations would take months and analysis by hand would not be feasible for a clinical test run on thousands of infants annually.

***Claim Rejections - 35 USC § 112, ¶ 6***

Claim 21 was rejected under section 112, paragraph 6, in connection with its means-plus-function recitation and an identification of corresponding structure disclosed in the original specification.

Claim 21 has been amended hereby so that it no longer recites means-plus-function elements. It is supported for example by the system illustrated in Figs. 1a and 1b. For example see the following listing relating claim language to disclosure:

- a. acoustically presenting at least one modulated noise stimulus to at least one ear of the patient (see Fig. 1a, component 42);
- b. recording steady-state response data related to the patient's response to said at least one modulated noise stimulus (see Fig. 1a, component 14, 30, 32 );
- c. performing signal analysis on said steady-state response data to generate frequency domain result data (see Fig. 1a, component 46, 48);
- d. statistically evaluating the frequency domain result data to determine the presence of at least one auditory steady-state response (For example, see Fig. 1a, component 50, paragraphs [0077]-[0085]); and
- e. providing a pass/fail result which indicates whether said subject has passed or failed said screening test. (For example, see Fig. 1a, component 40, paragraph [0036], [0054]).

***Claim Rejections - 35 USC § 102***

Claims 1-11, and 20-21 were rejected under 35 U.S.C. 102(e) over John et al (2001/0049480 A1).

The inventor named in this application also is named as an inventor named in the applied reference. To the extent the applied reference might disclose inventive features of the claims in this application remaining after the entry of this response, such inventive features are the contribution of the inventor named in this application.

Claims 1-3, 7, 9, 20-21, and 40-43 were rejected under 35 U.S.C. 102(b) over John et al (MASTER: A Windows Program ... 2000). Applicant submits that the claims as amended hereby are directed to screening rather than solely diagnostic tests, and are not anticipated by the applied reference at least for this reason. The applied reference discusses the use of MASTER to provide a modulated stimulus, record responses, analyze the acquired signals and evaluate the result data to determine the presence of an auditory response, but it is submitted that it does not contain all elements of a claim directed to a method or system embracing a recognition that presence or lack of a response would provide a "pass/fail result" as recited in the claims amended hereby.

Claims 1-3, 7, 9, 20-21, and 40-43 were under 35 U.S.C. 102(b) over John et al (MASTER: Stimulus and Recording Parameters, 1998). Again, it is submitted that the applied reference does not contain all elements of a claim directed to a method or system embracing a recognition that presence or lack of a response would provide a "pass/fail result" as recited in the claims amended hereby. Moreover, on page 61 of the cited reference it is stated that recordings lasted "between 7 and 20 minutes", where the maximum time for a screening test would be 3-5 minutes, with most patients requiring about 1-2 minutes.

If a petition for an extension of time is required to make this response timely, this paper should be considered to be such a petition. The Patent Office is hereby authorized to charge any

required fees in connection with this amendment, and to credit any overpayment, to our Deposit Account No. 03-3125.

Respectfully submitted,



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